Before doing that it should be pointed out that Claim 1 of the application has now been amended to more clearly identify the non-obvious features of the invention. In particular, Claim 1 has been amended to call for the following combination of features: (1) a system comprising a plurality of elongated inserts and a deployment instrument for deploying those inserts into respective ones of the channels, (2) at least a portion of each of the inserts being formed of a resorbable material to stimulate angiogenesis in the myocardium, (3) the inserts when deployed within the channels being resistant to migration and not significantly limiting the contractility of the being's heart, and (4) the resorbable portion of the inserts resorbing over time in the selected portion of the myocardium and serving to elicit a foreign body or healing response in the tissue making up the selected portion of the myocardium to form plural blood-carrying lumens in the myocardium and enhance to flow of blood to the myocardium even if the channels close down after said resorbable portion of said inserts has resorbed.

There is full support in the specification for the amendment to Claim 1, see in particular pages 13, 16 and 21 and Figs. 3, 7, 10c, and 14 - 17. For example in the Fig. 14 there is shown the wall of a diseased heart immediately after deployment of an insert (as can be seen in that Figure there is minimal vasculature adjacent the channel in which the insert is placed). Fig. 16 is described on page 13 as showing the wall of the heart "some time after the deployment of the insert so that the insert has elicited a foreign body response in the myocardium to stimulate angiogenesis and revascularization" and the figure itself shows such increased vasculature. Fig. 17 is described on page 13 as showing the heart "after the insert has been absorbed . . . whereupon the lumen may

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shrink in diameter" (close down). Fig. 17 shows that there is further increased vasculature adjacent the lumen. Virtually all of page 16 describes the angiogenic action of the subject resorbable inserts of this invention. On page 21 the operation of an insert is described as follows:

> Over time the body's natural healing response to the "foreign" insert deployed within the lumen 9 will result in increased vasculature contiguous with the lumen, like shown in Fig. 17. It should be noted that in Fig. 17 the relevant cardiac portion is shown after the insert has either been absorbed or removed, but the result is the same, namely, the formation of new capillaries and vessels as a result of the body's natural healing response and angiogenesis caused by the one-time presence of the insert within the lumen.

Thus, there is clear support for the feature of the insert stimulating angiogenesis.

Moreover, it should be clear that the subject invention need not rely on the channel in which the insert is deployed remaining open at all. In this regard see the embodiment of Fig. 7 where the insert is deployed in a entirely isolated channel. Clearly this embodiment is not relying upon blood from the heart's chamber entering the lumen for feeding the myocardium and the capillaries or other vasculature adjacent the channel. It is the angiogenic effect of the insert that provides the beneficial effect. So too, the embodiments of the invention shown in Figs. 3 and 10c, do not rely on the blood from the heart's chamber entering into the channel. Thus, there is clear support for the limitation

"even if the channels close down after said resorbable portion of said inserts has resorbed."

In short, it should be clear from Claim 1, as amended, that the subject invention makes use of the resorbable material for stimulating angiogenesis in the myocardium to enhance the vascularization thereof. This can be accomplished even if the channel in which the insert of the subject invention has been deposited in closes down (such as shown in Fig. 17) or never was in communication with a chamber of the heart (such as shown in Figs. 3, 7 and 10c)

In contradistinction the Hussein Patent 5,878,751 relies on a different mechanism to effect TMR, namely, keeping a channel that is formed in communication with a chamber of the heart open so that blood can flow from that chamber into the channel. To that end, Hussein uses stents that are designed to hold the channels open and to remain in place to keep them open so that blood can flow from the heart chamber 24 contiguous therewith through the hollow inserts into the myocardium 25. Thus, Hussein would not have considered making his stents resorbable - his sole focus is to keep the channels open so that blood from the ventricular chamber can enter into the myocardium through the channels.

The subject invention makes use of plural inserts, with at least a portion of each insert being resorbable to disappear after time. The resorbable nature of the insert results in angiogenesis (the formation of new capillaries or other vasculature) as the insert is resorbed to result in a revascularized myocardium, like shown in Fig. 17. In that figure some of the new capillaries 7 are in fluid communication with the lumen 9 in which the

insert had been located. In Fig. 17 the channel is shown closing down, i.e., it is smaller than that initially formed. With the subject invention, even if that lumen closes completely after the resorption of its insert, there will still be increased vasculature to feed the myocardium (albeit not from the contiguous heart chamber) resulting from the angiogenic aspect of the insert, as also discussed above. As also discussed above even if the lumen formed by the insert does not communicate with the interior of the ventricular chamber, the formation of the lumen and the deployment of the inventive insert therein serves to bridge those capillaries that are contiguous with the lumen so that blood can be carried from capillaries in one portion of the myocardium to capillaries in a remote portion thereof by the lumen bridging those capillaries and in addition the angiogenic action of the insert will result in additional vasculature created at the location of the insert.

Thus, it is respectfully submitted that the specification clearly shows that the resorbable nature of the inserts of the subject invention does provide criticality and/or unexpected results. In fact, the subject invention provides a function unrecognized by Hussein, namely, the revascularization of the myocardium without requiring TMR inserts or stents to remain in place and in communication with the ventricular chamber to achieve that function. The importance of Hussein's stents remaining in place to keep the channel open to the ventricular chamber cannot be dismissed or ignored, since Husssein's patent specification is replete with statements indicating the criticality of that action. See for example:

(1) Column 1, lines 43 - 46 where it states:

"While clinical studies have demonstrated improvements in patient status following TMR, histological studies indicate that the channels created for TMR tend to close shortly after the procedure."

(2) Column 1, lines 50 - 53 where it states:

"It would be desirable to develop means for maintaining the patency of TMR channels created within the myocardium."

(3) Column 1, lines 55 - 57 where it states:

"This invention provides the desired means for producing transmyocardial channels that are likely to remain patent..."

(4) Column 2, lines 10 - 15 where it states:

"The limitation of needle-made channels is early closure (Pifarre, 1969). The disclosed stenting approach offers a possible solution to the early closure problem, while taking advantage of simple and effective needle-made channels for TMR.

(5) Column 2 lines 17 - 19 where it states:

"This invention provides stent and needle means for creating and maintaining a patent lumen in the diseased myocardium.

(6) Column 2, lines 36 - 40 where it states:

(6) Column 2, lines 36 - 40 where it states:

> "The stent is designed so as to maintain an adequate pressure gradient between the left ventricle and the myocardial tissue in order to maintain the flow from the ventricular cavity to the myocardial tissue of blood nutrients."

Thus, it should be clear beyond peradventure that Hussein considers one of the major problems with needle-made channels to be maintaining patency. He developed his non-resorbable stents to produce channels that "are likely to remain patent." In addition, his stents are designed to "maintain a pressure gradient between the LV and the myocardial tissue in order to maintain the flow . . . ."

Acceptance of the examiner's conclusion of obviousness of making the Hussein stent partially or completely resorbable would require ignoring the entire teaching of Hussein (a resorbable insert would eventually degrade, not maintain the pressure gradient and, hence, allow the channel to close).

In view of the forgoing it is respectfully submitted that Claim 1 is patentable over Hussein. Moreover, since Claims 2 - 19 depend directly or indirectly upon Claim 1, those claims are also submitted to be patentable over Hussein.

All of the claims of the application were also rejected on the basis of "obviousness-type" double patenting. Enclosed herewith is a Terminal Disclaimer (along with a Certificate Under 37 CFR 3.73(b) Establishing Right of Assignee To Take Action), that as submitted should overcome the obviousness-type double patenting rejection of the claims.

In view of the foregoing amendments and remarks it is respectfully submitted that Claims 1 - 19, all of the claims in this application, are allowable and such favorable action is respectfully requested.

Applicants are mindful of the requirement to submit acceptable formal drawings in this application, but intend to defer such action until receipt of an indication of allowability of the subject matter of this application.

In the event that the foregoing amendment does not result in the allowance of this application and there is(are) any issues which need to be resolved, the undersigned respectfully requests that Examiner Truong give the undersigned a telephone call to try and resolve any such outstanding issue(s).

Respectfully submitted,

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